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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER	
SMITH, CAROLYN L	

ART UNIT	PAPER NUMBER
1631	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	09/496,893	BROWN, STEPHEN J.	
	Examiner	Art Unit	
	Carolyn Smith	1631	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *25 September 2008*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *83-98* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *83-98* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicants' submission, filed 9/25/08, has been entered.

Claims 83-98 are herein under examination.

Claims Rejected Under 35 USC § 112, First Paragraph

The following is a quotation of the first paragraph of 35 U.S.C. § 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 83-98 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor, at the time of the invention was filed, had possession of the claimed invention. This rejection is maintained and reiterated for reasons of record.

NEW MATTER

Applicant points to support for the claim amendments in the drawings as originally filed, for example, in FIGS. 1, 2, 10, 11A, 11B, 12A, 12B and 19, and in the specification as originally filed, for example, on page 16, line 4-14, on page 23, lines 8-33, on page 25, lines 12-19, on page

30, lines 5-14, on page 31, line 27 through page 32, line 21, on page 33, lines 23-33 and on page 34, line 32 through page 35, line 11.

There does not appear to be adequate written description for "selecting one or more disease-influencing genes needed to be processed for medical research" (claims 83, 90), "that represents a subset of said genotype information associated with each of said groups" (claim 83), "identifying one or more individuals having a disease-influencing gene" (claim 90), "identifying individuals having a disease-influencing gene" (claim 94), and "to identify one or more individuals having a disease-influencing gene" (claim 94).

While specification (page 11, line 24) and Figure 17 recite "selecting individuals", they do not recite "selecting one or more disease-influencing genes needed to be processed for medical research" which differs in scope. While the Figure 17 recites "identify gene" (518) and Figures 8 and 10 show a report for a single patient, these do not provide adequate written support for a display "that represents a subset of said genotype information associated with each of said groups" which differs in scope. While Figure 17 recites "identify gene" (518), this does not provide adequate written support for "identifying individuals having a disease-influencing gene" (claim 94) and "to identify one or more individuals having a disease-influencing gene" (claim 94) which differs in scope.

Because the limitations "selecting one or more disease-influencing genes needed to be processed for medical research" (claims 83, 90), "that represents a subset of said genotype information associated with each of said groups" (claim 83), "identifying one or more individuals having a disease-influencing gene" (claim 90), "identifying individuals having a disease-influencing gene" (claim 94), and "to identify one or more individuals having a disease-

influencing gene" (claim 94) do not appear to have written support in the specification, claims, and/or drawings, as originally filed, these phrases are considered to be NEW MATTER. Claims 84-89, 91-93, and 95-98 are also rejected due to their dependency from claims 83, 90, and 94.

Applicant argues that support for the phrase "selecting one or more disease-influencing genes needed to be processed for medical research" can be found on page 11, lines 8-19, of the specification. It is noted that the passage recites "to find disease-influencing genes" which is different from "selecting one or more disease-influencing genes". To find and to select are not commensurate in scope as "find" may indicate that the information was not previously known, while "select" can be interpreted, for example, to be a user action of deciding which genes from an already verified list to choose. It is noted that "to be processed for medical research" and "to use the disease-influencing genes or substances to find drug candidates or drug targets" are not commensurate in scope as the first mention phrase is broader. Processed for medical research encompasses activities such as clinical trials, developing pharmaceuticals and kits, diagnosing disease, etc. which is broader than just finding drug candidates or targets.

Applicant argues that "using environmental information about an individual in conjunction with the individual's genotype to find disease-influencing genes" in the specification provides adequate written support for "to identify one or more individuals having a disease-influencing gene". This statement is found unpersuasive as the first phrase is finding genes which is vastly different from identifying individuals. Applicant argues that the phrase "that represents a subset of said genotype information associated with each of said groups" is supported by differences in Figures 15-18 and 20 found when comparing the genotype information of individuals between

groups would reasonably be described as a subset of the total genotype information associated with the groups. This statement is found unpersuasive as grouping individuals, categorizing each group, and finding a disease-influencing substance (i.e. Figure 19) does not mention or infer any subset of genotype information associated with each group. Applicant argues another example provided in the specification as originally filed is the use of data mining techniques to find differences in gene sequences (see page 31, lines 1-10 of the specification) and argues it is inherent that a report of the results of the data mining (e.g., individual gene sequences A and B in the example) would be generated or else the data mining would not be useful or advantageous. This statement is found unpersuasive as the passage provides support for finding and identifying a gene, not representing a subset, which is differs in scope. Applicant argues, in connection with FIGS. 2 and 10, the specification states that specific techniques for writing a report generator program to display data are well known in the software art (e.g., see page 24, lines 12-21 of the specification as originally filed). This statement is found unpersuasive as displaying data does not represent a subset.

Claim Rejections – 35 U.S.C. 112, First Paragraph

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Factors to be considered in determining whether a disclosure would require undue experimentation have been summarized in *Ex parte Forman*, 230 USPQ 546 (BPAI 1986) and reiterated by the Court of Appeals in *In re Wands*, 8 USPQ2d 1400 at 1404 (CAFC 1988). The factors to be considered in determining whether undue experimentation is required include: (1) the quantity of experimentation necessary, (2) the amount or direction presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claims. The Board also stated that although the level of the skill in molecular biology is high, the results of experiments in genetic engineering are unpredictable. While all of these factors are considered, a sufficient amount for a *prima facie* case are discussed below.

LACK OF ENABLEMENT

Claims 83-98 are rejected under 35 U.S.C. § 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the claimed invention.

This rejection is maintained and reiterated for reasons of record.

It is well known that the Human Genome Project has revealed that the number of human genes is in the range of 30,000. Even this number is controversial. Applicant's invention is

directed to the clustering of individuals into groups based on responses to queries and then determining gene differences between groups in order to determine gene differences for selecting disease-influencing genes or identifying individuals having a disease-influencing gene. It is also well known that a multitude of polymorphisms exists in human genes caused by environmental factors such as chemicals or cosmic rays. These complications result in an unpredictable length and difficulty in a research project that simply clusters individuals via queries regarding the behavior or other characteristics to then isolate or focus on one or more disease-influencing gene(s), even if guided by disease risk factors. It is known that some genetic sequences are correlated with particular diseased individuals, but that each of these sequences was elucidated by lengthy research projects where the findings of the gene sequence was difficult and unpredictable. Thus, the clustering of individuals, which has been known for many diseases already has not predictably resulted in gene identification, nor will the practice of the instant invention predictably result in the selection or identification of disease-influencing gene(s) or the identification of individuals having a disease-influencing gene. The publication of Doberstein et al. (previously mailed with a previous office action) was cited regarding paragraphs 0003-0008 to support the numerous difficulties involved in relating gene sequences to other factors even utilizing modern bioinformatics tools. It is also noted one skilled in the art would not scientifically conclude that simply comparing genotype information (instant claim 83) or comparing genotype information based on groups formed using query responses (instant claims 90 and 94) results in the identification or selection of a disease-influencing gene or identification of individuals having a disease-influencing gene. Furthermore, selecting genes needed to be

processed for medical research further documents the undue experimentation recited in these claims. For these reasons, the instant claims are rejected due to a lack of enablement.

Applicant argues FIGS. 1, 2 and 13-20 along with the respective descriptive text describes the subject matter of the presently pending claims in such a way as to enable one skilled in the art to which it pertains or with which it is most connected, to make and/or use the claimed invention. In particular, the specification provides numerous examples of genotype information and sources (e.g., companies) from which genotype information can be received or obtained (see page 4, line 14 through page 9, line 25 of the specification). The specification further provides examples of comparing genotype information based on groups of individuals formed based upon responses to scripted queries (see FIGS. 16, 18 and 20 as originally filed). These statements are found unpersuasive as polymorphisms that exist in human genes that result in an unpredictable length and difficulty in a research project that simply clusters individuals via queries regarding behavior or other characteristics to then isolate or focus on one or more disease-influencing genes. The Office Action states that Doberstein et. al. (U.S. Pub. No. 2003/0068649; hereinafter Doberstein) was cited regarding paragraphs 0003-0008 to support the position that numerous difficulties are involved in relating gene sequences to other factors even utilizing modern bioinformatics tools. Applicant summarizes portions of Doberstein, including "[t]he fundamental difficulties associated with working with large collections of nucleic acid sequences, such as genetic libraries, are alleviated by linking the expressed peptide with the genetic material which encodes it." (paragraph [0006], lines 1-4 of Doberstein). Doberstein then describes commonly used methods of linking proteins to coding nucleic acid molecules (see

paragraphs [0006]-[0007] of Doberstein). Doberstein further states that the invention disclosed by Doberstein provides a genetic library which allows easy association of a variant or unknown peptide and its coding sequence and a method of use (see paragraph [0008] of Doberstein). Applicant argues that the statement in the Office Action that "[t]hus, the clustering of individuals, which has been known for many diseases already has not predictably resulted in gene identification" (see page 5, lines 18-21 of the Office Action) is directly contradicted by the example of Myriad Genetics, Inc. on page 7, lines 12-21 of the specification as originally filed. This statement is found unpersuasive as the art is considered unpredictable as noted by Doberstein et al. (0004). Applicant argues that Examiner made a determination of enablement based on personal opinion. This statement is found incorrect as the determination has been based on the Wands factors and fully supported by objective evidence from Doberstein as to the unpredictability in this art. Applicant argues that the experimentation is routine business which is found unpersuasive due to the unpredictable nature of the art which leads to undue experimentation.

Applicant argues that the rejection is obviated due to claim amendments. This statement is found unpersuasive as the claim amendments still recite the non-enabled elements as described above. Applicant summarizes claims 83, 90, and 94. Applicant argues that the claims are enabled because Figures 1, 2, and 13-20 along with respective text describe the subject matter presently claimed to enable one to make and use the claimed invention, particularly by examples of genotype information that can be received or obtained (pages 4-9 of specification) as well as examples of comparing genotype information based on groups of individuals. This statement is

found unpersuasive as this argument does not address the problem of "selecting one or more disease-influencing genes needed to be processed for medical research" or "identifying one or more individuals having a disease-influencing gene" as already discussed in the rejection above. Applicant summarizes Doberstein et al. Applicant argues that a patent need not teach, and preferably omits, what is well known in the art. Applicant adds that complex experimentation and numerous difficulties do not necessarily make experimentation undue, if the art typically engages in such experimentation. This statement is unpersuasive as it is well known that numerous difficulties involved in relating gene sequences to other factors even utilizing modern bioinformatics tools (as stated by Doberstein et al.) leading to unpredictable experimentation that qualifies as undue experimentation since it is not considered to be routine experimentation. As stated in MPEP 2164.03:

> The "predictability or lack thereof" in the art refers to the ability of one skilled in the art to extrapolate the disclosed or known results to the claimed invention. If one skilled in the art can readily anticipate the effect of a change within the subject matter to which the claimed invention pertains, then there is predictability in the art. On the other hand, if one skilled in the art cannot readily anticipate the effect of a change within the subject matter to which that claimed invention pertains, then there is lack of predictability in the art. Accordingly, what is known in the art provides evidence as to the question of predictability.

Applicant's arguments are deemed unpersuasive for the reasons given above.

Claims Rejected Under 35 U.S.C. § 112, Second Paragraph

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 83-93 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which the applicant regards as the invention.

These rejections are maintained and reiterated for reasons of record.

The preamble of claim 83 recites selecting one or more disease-influencing genes whereas the body of the claim recites selecting individuals, but not genes. In addition, the body of the claim recites generating a report representing a subset of genotype information, which is not necessarily one or more disease-influencing genes. Therefore, it is not clear if the preamble is intended to limit the method and what relationship is intended between the preamble and method steps. Claims 84-89 are also rejected due to their dependency from claim 83.

The preamble of claim 90 recites selecting one or more disease-influencing genes whereas the body of the claim does not recite selecting genes, but rather identifying one or more individuals having a disease-influencing gene. Therefore, it is not clear if the preamble is intended to limit the system and what relationship is intended between the preamble and body of the claim. Claims 91-93 are also rejected due to their dependency from claim 90.

Applicant argues that the mere fact that the body of the claim recites additional elements that do not appear in the claim's preamble does not render the claim indefinite. While this is

agreed, it is noted that a claim is indefinite when the preamble recites information that differs or is missing from the body of the claim, as in the current 35 USC 112, 2nd paragraph rejections. Applicant summarizes instant claims 83 and 90 and cites pages 7 and 11 of the specification. Applicant argues that comparing genotype information and generating a report would be reasonable steps in a method for selecting one or more disease-influencing genes. While they may be part of the method, it is unclear if the preamble is intended to limit the method and what relationship is intended between the preamble and the method steps. It is also noted that while the claims can be read in light of the specification, portions of the specification may not be read into the claims.

Conclusion

No claim is allowed.

This is a request for continued examination. All claims are drawn to the same invention claimed in the earlier application and could have been finally rejected on the grounds and art of record in the next Office action if they had been entered in the earlier application. Accordingly, **THIS ACTION IS MADE FINAL** even though it is a first action in this case. See MPEP § 706.07(b). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after

the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no, however, event will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Papers related to this application may be submitted to Technical Center 1600 by facsimile transmission. Papers should be faxed to Technical Center 1600 via the PTO Fax Center. The faxing of such papers must conform to the notices published in the Official Gazette, 1096 OG 30 (November 15, 1988), 1156 OG 61 (November 16, 1993), and 1157 OG 94 (December 28, 1993) (See 37 CFR §1.6(d)). The Central Fax Center number for official correspondence is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Carolyn Smith, whose telephone number is (571) 272-0721. The examiner can normally be reached Monday through Thursday from 8 A.M. to 6:30 P.M.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Marjorie Moran, can be reached on (571) 272-0720.

October 23, 2008

/Carolyn Smith/
Primary Examiner
AU 1631